

URGENT

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: RONALD L. GRUDZIECKI *1ARB*
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

*Response to Written
Opinion due 3-3-00*

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
RECEIVED**PCT**

FEB 07 2000

WRITTEN OPINION

DOCKETED
(PCT Unit 15)Date of Mailing
(day/month/year)

03 FEB 2000

Applicant's or agent's file reference

028870-168

REPLY DUE

within ONE months
from the above date of mailing

International application No.

PCT/US99/00391

International filing date (day/month/year)

22 JANUARY 1999

Priority date (day/month/year)

23 JANUARY 1998

International Patent Classification (IPC) or both national classification and IPC
Please See Supplemental Sheet.

Applicant

USBIOMATERIALS CORPORATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 23 MAY 2000

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOHN PAK

Telephone No. 308-1235

2-7.00
all

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To: RONALD L. GRUDZIECKI
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Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

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WRITTEN OPINION

International application No.

PCT/US99/00391

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

☒ the international application as originally filed.

☒ the description, pages 1-7 , as originally filed.

pages NONE , filed with the demand.

pages NONE , filed with the letter of _____

☒ the claims, Nos. 1-8 , as originally filed.

Nos. NONE , as amended under Article 19.

Nos. NONE , filed with the demand.

Nos. NONE , filed with the letter of _____

☒ the drawings, sheets/fig NONE , as originally filed.

sheets/fig NONE , filed with the demand.

sheets/fig NONE , filed with the letter of _____

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig NONE

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

WRITTEN OPINION

International application No.

PCT/US99/00391

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	<u>1-8</u>	YES
	Claims	<u>NONE</u>	NO
Inventive Step (IS)	Claims	<u>NONE</u>	YES
	Claims	<u>1-8</u>	NO
Industrial Applicability (IA)	Claims	<u>1-8</u>	YES
	Claims	<u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-8 meet the criteria set out in PCT Article 33(2), because no single prior art reference can be found that expressly discloses a method of treating inflammatory symptoms related to skin disorders by topically applying non-interlinked, particulate bioactive glass, as claimed.

Claims 1-8 meet the criteria set out in PCT Article 33(4), because the claimed invention finds industrial applicability in the treatment of skin disorders.

Claims 1-8 lack an inventive step under PCT Article 33(3) as being obvious over WO 97/17401 in view of Shimono et al (US 5,290,544).

WO 97/17401 teaches that bioactive glasses such as 45S5 BIOGLASS® product (page 6) bond to a variety of soft tissues such as skin (paragraph bridging pages 4 and 5). Composition makeup of bioactive glass includes SiO₂, Na₂O, CaO and P₂O₅ (page 4, lines 5-13).

Shimono et al. (US 5,290,544) disclose the use of certain soluble glass substances to contain antibacterial agents for formulations such as skin lotion (column 1, lines 46-53; column 2, lines 45-48).

It is noted that all claims are open to adding therapeutic agents to bioactive glass to treat inflammation. In this regard, to incorporate such agents in bioactive glass, which itself is known to elicit beneficial physiological responses to soft tissues such as the skin, would have been well within the skill of the routineer in the art since doing so would assist in the delivery of anti-inflammatory agents or skin compatibility adjuvant agents. Therefore, the claimed invention, as a whole, would have been obvious to the routineer in the art at the time the invention was made.

For these reasons, the claims lack an inventive step under PCT Article 33(3).

----- NEW CITATIONS -----

WO 97/17401 A1 (BONFIELD et al.) 15 May 1997, see pages 4-6.

US 5,290,544 A (SHIMONO et al.) 01 March 1994, see column 1, lines 46-53, column 2, lines 45-48.

WRITTEN OPINION

International application No.

PCT/US99/00391

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(6): A61K 9/14, 33/00, 33/06, 33/08, 33/16, 33/22, 33/42. and US Cl.: 424/400, 401, 484, 489, 601, 602, 606, 657, 660, 675, 688, 692, 722, 724; 514/830, 859, 861, 862, 863, 864, 865, 886, 887, 951.